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EXAMINER	
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ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/725,304	LINDBERG ET AL.	
	Examiner	Art Unit	
	Danton DeMille	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The amendment filed 25 February 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The claims now require the first and second tube to be "outside of the tracheal tube and the cuff". There appears to be no support in the original specification for the first and second tube to be outside of the tracheal tube and the cuff. Applicant is relying on the figure 1 to show support for such structural relationship. Figure 1 is merely a schematic representation of the overall relationship between parts. First 8 and second 10 tubes are shown attaching to the apex of the spherical shape of the cuff 6. If the first and second tubes were in fact extending out of the apex of the spherical shape of cuff 6 they would be extending perpendicular to the tracheal tube and more importantly extending perpendicular to the trachea of the patient. The tubes would be scraping against the inside walls of the trachea. The tubes would also be loosely dangling inside the trachea possibly getting tangled and causing further irritant as is passes down the trachea. When the cuff inflates, the cuff would press the tubes perpendicularly at a pressure point against the side wall of the trachea. Causing further damage to the trachea. No one of ordinary skill in the art would have the separate inflation tubes extend perpendicularly of the inflation cuff to possibly damage the trachea. One of ordinary skill in the art would incorporate the tubes with the tracheal tube such as taught by Kruse.

Additionally, the new line 22A added to the drawings and the language added to the specification appears to be new matter. The drawings and specification now requires that the

therapeutic agents are injected to the circulation line 8, 10 which introduces gases inside the balloon cuff 6. The original specification stated that the therapeutic agents were introduced in the patient's trachea and further down to the lungs. For the therapeutic agent to be introduced further down into the lungs it would appear that a tube would have to extend further down the tracheal tube than where the cuff is located. The cuff is located in the middle of the tracheal tube and therefore in order for the agent to be introduced "further down to the lungs" a tube attached to the tracheal tube extending to the end of the tracheal tube would provide that function. Now restricting the application of the agent to be introduced only from the cuff would appear to be new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

It is not clear how much weight or structural details can be given to the limitation of the first and second tubes being outside the tracheal tube and the cuff. While figure 1 shows the first and second tube attached to the apex of the inflatable cuff, figure 1 appears to be a schematic drawing to show that there are separate lines that are connected to the cuff. Drawing lines down the tracheal tube would be associated with the tracheal tube and it would not be clear that these lines are intended to be connected to the inflatable cuff. Lines down the sides of the tracheal tube would not clearly show that they are intended to communicate with the inflatable cuff. Figure 1 clearly shows that the first and second tubes are to individually connect to the inflatable

cuff however, figure 1 merely shows this schematically and not intended to structurally limit the invention.

Claims 1, 3-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not adequately described as set forth in the above rejection to the specification.

It is not clear how much structural details can be given to the limitation of the first and second tubes being outside the tracheal tube and the cuff as set forth in the objection to the amendment and specification.

Claim Rejections - 35 USC § 103

Claims 1, 3-5, and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kruse et al. US 5,957,839.

As to claim 1, Kruse discloses a medical device (see fig. 1) comprising: a selectively permeable cuff (14). Although Kruse is silent on the cuff can be configured to be positioned in the trachea of a subject, however, Kruse in figure 1 clearly shows that his device has a tube (24, 26, 28) and a cuff (14) and the distal end of the tube containing the cuff (14) can be inserted into a person's trachea. Kruse teaches "Catheter 10 has a distal, intracorporeal end 12 which is placed within an organ or tissue of a patient's body by introduction through a body orifice, such as the nose, mouth, or rectum. Catheter distal end 12 has a distensible, inflatable, gas-permeable tonometry vessel 14 situated adjacent thereto" column 5, lines 57-62. Clearly the device of Kruse is not limited to any one intended use. One of the intended uses of the device is to be inserted into the mouth to be placed adjacent the desired organ or tissue. Kruse teaches the device can enter the mouth and therefore it can enter the trachea of the patient. The device is

intended for continuous monitoring of tissue gas composition and pH. The trachea and lungs are one of the possible locations for monitoring tissue gas composition and pH. Kruse does not state that the device cannot be used for such intended use. Therefore the tube of Kruse is capable of being placed in the trachea.

Figure 1 of Kruse shows a first tube 22 that is a separate tube from the catheter tube that is used for ingress of gas within the cuff 14. A second tube 20 is also a separate tube from the catheter tube that is used for egress of gas within the cuff 14. The tube/catheter (24) has a separate lumen with end orifice (30) and side orifices (32). Broadly both the first and second tubes are outside of the tracheal tube because they are separate tubes located on the outside of the tracheal tube. They also have a portion that is outside of the cuff 14.

"Distal side orifices (32) are provided to obviate occlusion of all safety pressure relief lumen orifices by contact with tissue during a procedure such as aspiration" column 6, lines 14-17. If gases can pass through the tracheal tube, breathing gases can pass through the tracheal tube. Clearly the tube/catheter (24) is capable of allowing the subject respiration though the tracheal tube since gas is intended to flow therethrough. Furthermore, Kruse in column 12 lines 2-4 discloses that the distal end of the tube/catheter is placed in the animal's stomach via the mouth, thus, suggest that the distal end containing cuff can be placed within other similarly sized passages such as a trachea when passed though the mouth of the subject.

Kruse discloses a first tube (20) having a first end in fluid communication with an interior of the cuff (see fig. 1) and having an opposite, second end (connecting 56); a second tube (22) having a first end in fluid communication with the interior of the cuff (see fig. 1) and having an

opposite, second end (connecting 56); a pumping device (52) connected to the respective second ends of the first and second tubes that circulates a fluid through the interior of the cuff (col. 8, lines 34 and 35); and said cuff comprising a membrane (col. 6, lines 30-33) that is selectively permeable to a specific substance (CO2 gas or "particular gas to be measured", see col. 11 line 61) relative to said fluid, said membrane being disposed to allow transfer through said membrane of said substance from an exterior of the cuff to the interior of the cuff and an exterior of the cuff (since the membrane is permeable to gas, it will allow transfer of gas from the trachea ("exterior") to tube ("interior") via the membrane, see also col. 6, lines 30-33), and analysis unit (72) in fluid communication with said flow path (see fig. 1) tat analyzes said fluid with regard to content in said fluid of said substance that has mixed with said fluid from the exterior of the cuff (see col. 10 lines 63-68 and col. 11 lines 1-24). Therefore Kruse teaches all of the positive structural limitations. The only difference between the claims and Kruse is the intended use in the trachea. As set forth above, Kruse suggests such intended use since Kruse teaches the device can used to test any organ or tissue in the body by introduction through the mouth. To any extent it is felt that there is some unclaimed limitation that is missing from Kruse it would have been obvious to one of ordinary skill in the art to modify Kruse such that it can be used in the trachea to test tissue within the trachea or lungs.

As to claim 3, Kruse discloses the analysis unit includes a calculation unit (76) that quantitatively determines an amount of said specific substance in said fluid relative to a predetermined normal amount (col. 10, lines 63-68, and col. 11, lines 1-24).

As to claim 4, Kruse discloses the medical device comprises a dosing unit (46) in fluid communication with said flow path that administers a dose of a medicament into said fluid (col. 7, lines 43-59).

As to claim 5, Kruse discloses wherein said analysis unit includes a calculation unit (76) that quantitatively determines an amount of said substance in said fluid relative to a predetermined normal amount (see col. 12 lines 30-40 where measured CO2 values are compared with a laboratory value/predetermined normal amount), dosing unit comprises at least one reservoir (a syringe inherently has a reservoir/space where gas will be held inside 46) containing at least one additive (substance introduced by the syringe) corresponding to said substance, said dosing unit including said additive from said reservoir in said medicament if said analysis unit determines that said amount of said substance in said fluid is below said predetermined normal amount (see col. 9 lines 53-57).

As to claim 8, Kruse discloses 58 that measures partial pressure of CO2 at any point in circuits 22, 42, 20 (see col. 10 lines 23-25), thus, when the dosing unit including said additive, the analyzing unit inherently analyzes the fluid with regard to content in said fluid of said substance that has mixed with said fluid from said exterior of the cuff and said medicament since analyzing unit would analyzed total fluid content inside the tube in order to determine CO2 concentration.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. and in view of Schultze US 4,141,364.

As to claim 6, Kruse lacks wherein said cuff comprises at least one partition wall that partition the interior of said cuff into multiple chambers. However, Schultze teaches endotracheal

tube cuff with multiple chambers (see figs. 7 and 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kruse in order to provide multiple chambers because it is known in the art as taught by Schultze. Kruse further lacks each chamber having a first chamber tube with a first chamber tube end in fluid communication therewith and a second chamber tube with a first chamber tube end in fluid communication therewith, and wherein said first chamber tube has a second chamber tube end and said second chamber tube has a second chamber tube end in fluid communication with said pumping device for circulation of respectively separate fluids through the multiple chambers. However, since Kruse teaches at least two tubes are in communication with the cuff at a different location within the cuff, and one end of each tube is connected to a pumping device, it would have been obvious to have each tubes of Kruse connected to separate chambers of Schultze. It would have been further obvious to have multiple tubes (i.e. first and second chamber tubes of first and second chamber as claimed) connecting to the cuff because it has been held that mere duplicate of tubes only requires routine skills in the art. Furthermore, it would have been obvious to one of ordinary skill in the art to increase the number of tubes to expedite fluid circulation within the medical device.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. and in view of Hanson et al. US 5,985,307 and in further in view of Walther et al. US 6,660,833 B1.

As to claim 7, Kruse lacks wherein said membrane is permeable to at least one protein, as said substance, selected from the group of proteins consisting of SP-A, SP-B, SP-C and SP-D that are present in surfactant. However, Hansen teaches a balloon cuff membrane device that can

be used to deliver therapeutic agent in the respiratory tree (see col. 2, lines 44 and 45) to treat a variety of disease syndromes (see col. 18, lines 55 and 56). Although Hansen's device is permeable to protein (i.e. antibody, see col. 26, line 55), Hansen however is silent on the claimed protein. However, Walther teaches respiratory distress syndrome therapy using peptide analogs of human SP-B that mimics human surfactant protein B (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kruse in order to provide a membrane that allowed protein to pass though in the respiratory tree for the purposes of treating respiratory disease syndrome as taught by Hansen and further modify the membrane to be selective to SP-A for the purposes of treating respiratory distress syndrome as taught by Walther.

Response to Arguments

Applicant admits that figure 1 is intended to be a schematic illustration. Therefore no clear structural relationships can be taken from figure 1. First and second tubes are shown connecting directly to the cuff however this is shown schematically to clearly show that they are intended to be connected to the cuff 6. Drawing lines down the sides of the tracheal tube would not clearly show with what these tubes are intended to communicate. It is doubtful that the first and second tubes extend at right angles to the tracheal tube and would extend at right angles to the trachea. This would cause unnecessary scraping of the tubes as it is inserted down the trachea and upon inflation of the cuff would try to poke a hole in the side of the trachea. One of ordinary skill in the art would not attach the first and second tubes to the cuff at right angles to cause harm to the trachea. These structural details cannot be taken from the drawings therefore no structural details can be taken from the drawings.

Applicant argues that the tubes 20 and 22 of the Kruse device would have to be moved outside of the lumen 24 however, that is not the examiner's position. Kruse does not have to be structurally modified. The tubes 20 and 22 are already outside of the lumen 24. Tubes 20 and 22 are separate and distinct tubes that carry different gases from lumen 24. Broadly, tubes 20 and 22 are already outside of lumen 24. No modification is necessary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974. The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Danton DeMille/

11 May 2009

Danton DeMille
Primary Examiner
Art Unit 3771